

REMARKS

Applicant respectfully points out that the status of the Office Action mailed on September 11, 2006 was not indicated as either final or non-final on the Office Action Summary or in the text of the Office Action, and assumes that this action is non-final.

Claims 7-22 have been cancelled. Claims 23-30 are newly presented. Therefore, Claims 23-30 are now pending in the application. Support for the new claims can be found throughout the application, drawings and claims as originally filed and, as such, no new matter is presented. The Examiner is respectfully requested to reconsider and withdraw the rejections in view of the new claims appended and remarks contained herein.

REJECTION UNDER 35 U.S.C. § 102

Claims 7-9, 11-13 and 16 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Viegas et al. (U.S. Patent No. 5,587,175, herein recited as "Viegas"). This rejection is respectfully traversed. Claims 7-9, 11-13, and 16 are cancelled. Accordingly, this rejection is moot.

REJECTION UNDER 35 U.S.C. § 103

Claims 10, 14, 15, and 17-22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Viegas et al. in view of Chang (U.S. Patent No. 6,051,560). This rejection is respectfully traversed. Claims 10, 14, 15, and 17-22 are cancelled. Accordingly, this rejection is moot.

NEW CLAIMS

New claims 23-30 are added. Newly added Claims 23-30 recite a method for preservation and/or treatment against bacterial infection in an ophthalmological surgery site, comprising applying a pharmaceutical composition containing a viscoelastic substance, to make the composition directly contact an anterior chamber, endothelium of cornea, lens capsule and a passage of aqueous humor.

Viegas describes aqueous mixtures of a film forming, water soluble polymer and an ionic polysaccharide, optionally containing a latent counter-ion to gel the polysaccharide. (Col. 5, lines 23-27). Moreover, Viegas describes gel compositions that can be peeled away or allowed to be absorbed over time. (Col. 5, lines 49-52).

The compositions of Viegas are described as being contemplated for protection of the outer surface of the cornea. "The drug delivery vehicles and corneal protective shield compositions of the invention are an improvement over those compositions used in the prior art methods of ophthalmological drug delivery..." (Col. 9, lines 15-18). The Examples cited by the Examiner are all related to laser ablatable corneal mask or protective corneal shields. Viegas does not disclose protection for structures including anterior chambers, endothelium of the cornea, lens capsule, and passage of aqueous humor. The claimed invention is directed to providing an antibacterial effect in the cavity of an eye ball and not on the surface of the cornea as disclosed by Viegas.

Chang deals with compositions containing chondroitin sulfate and sodium hyaluronate. (Col. 2, lines 1-6). Methods in Chang are described for using such a composition to aid in healing after trauma, for topical applications, irrigation during surgery, to protect corneal surface cells, during intraocular lens implantation, corneal

transplantation, and other intraocular surgical operations. Chang does not disclose the use of such compositions for prevention and/or treatment against bacterial infection. The claimed invention is drawn to intraocular surgery requiring the use of viscoelastic compositions. Viscoelastic materials can be protective materials for bacterial growth especially in intraocular surgery, for example endophthalmitis. Such infections are also aided by the fact that the natural antibacterial processes of clearance in the intraocular space are inhibited by the presence of the viscoelastic material (Specification as filed, page 14, lines 23-27).

The combined teachings of Viegas and Chang would not lead one of ordinary skill to arrive at the invention as claimed. Chang describes compositions that help protect corneal endothelial cells from trauma of surgery not to protect the intraocular space, including the anterior chamber from infection. Viegas refers to a topical application to corneal surfaces unrelated to the methods described in new Claims 23-30. The method of Viagas is unrelated to preventing infection in the intraocular space by administration of a viscoelastic composition. The combined references do not disclose or teach a viscoelastic composition useful for intraocular surgery that is made antibacterial to prevent infection due to residual viscoelastic material being left in the intraocular space.

There is no motivation in either of the references to combine an antibacterial and/or anti-inflammatory viscoelastic material in a method of preserving and/or treating a surgical site by contacting the antibacterial and/or anti-inflammatory viscoelastic material with intraocular structures such as the anterior chamber, endothelium of the cornea, lens capsule and passage of aqueous humor. Chang does not disclose a need

to protect or treat the intraocular space against infection. As such, there is no motivation to combine an antibacterial agent into the viscoelastic composition of Chang.

Moreover, the teachings of Viegas would lead a person of ordinary skill to leave the viscoelastic material in contact with the cornea: "The higher gel strength compositions upon contact with a counter-ion allow retention of the gel as an in situ formed corneal mask for long intervals." (Col. 11, lines 41-44). It is exactly the residence of viscoelastic material in the intraocular space that can help bacteria grow and cause inflammation and possibly blindness. (Specification as filed page 21, lines 24-27, and page 22, lines 1-17). The claimed invention provides a method to prevent and/or treat infection in the intraocular region when the viscoelastic material has not been completely removed after intraocular surgery. (Specification, page 14, lines 24-27).

No reference or combination of references illustrate why one of ordinary skill in the art would want to protect and treat the intraocular space from infection with a viscoelastic material that is antibacterial and/or anti-inflammatory. To combine hyaluronic acid and chondroitin sulfate for preventing and treating infection (rather than protecting tissues from trauma as disclosed in Chang), by contacting the intraocular space (not cornea surface) with a viscoelastic material incorporating antibacterial and/or anti-inflammatory agents to prevent bacterial infection, the requisite motivation to combine must be shown. As such, the references cited by the Examiner are trying to provide methods addressing two very different problems and actually teach away from the actual problem being solved in the present invention. The motivation to combine an antibacterial and/or anti-inflammatory agent to a viscoelastic material used

in intraocular surgery to prevent infection in the intraocular surgery site is certainly not provided by Viegas and Chang.

SECONDARY CONSIDERATIONS

Applicants bring to the Examiner's attention several arguments bearing on the secondary considerations of the presently claimed invention. It has been unrecognized until the filing of the present application that the injection of a routine medical material such as a viscoelastic material for intraocular use can lead to postoperative infection, for example bacterial endophthalmitis. The Applicants have received accolades by the Japanese Ophthalmological Society for their presentation on the claimed subject matter, and was selected as an "Excellent Lecture" and awarded at the 106th Annual Meeting of the Japanese Ophthalmological Society attached herein as an English translation as Exhibit A. Furthermore, the Applicants have reported their findings related to the use of an antibacterial agent mixed in a viscoelastic material to prevent and treat postoperative bacterial infections to peer reviewed journals and have subsequently been accepted for publication, also attached herein as Exhibits B and C.

The present inventors have also clarified the effect of adding an anti-bacterial agent to rabbit eyes after a bacterial challenge either separately from the viscoelastic material or included within the viscoelastic material. The results of these experiments were reported by the inventors at the 107th Annual Meeting of the Japanese Ophthalmological Society enclosed herein as Exhibit D. Significant differences were reported in the experiments outlined in Exhibit D. When the antibacterial agent is added to the intraocular space as a separate solution, 15 of the 16 rabbit eyes were found to

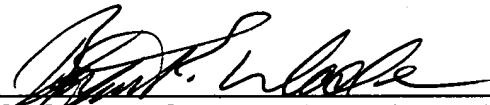
be endophthalmitis positive, whereas only 3 of 16 rabbit eyes were found to be endophthalmitis positive when the antibacterial agent was mixed intimately with the viscoelastic material as claimed herein. (See also Exhibit C).

CONCLUSION

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office Action and the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (248) 641-1600.

Respectfully submitted,

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By: 
G. Gregory Schivley, Reg. No. 27,382
Bryant E. Wade, Reg. No. 40,344

HARNESS, DICKEY & PIERCE, P.L.C.
P.O. Box 828
Bloomfield Hills, Michigan 48303
(248) 641-1600

GGs/FEA/ng/lf-s